

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 32043P WO	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2004/013535	International filing date (<i>day/month/year</i>) 29 November 2004 (29.11.2004)	Priority date (<i>day/month/year</i>) 28 November 2003 (28.11.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DEVELOGEN AKTIENGESELLSCHAFT		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p>	<p>Date of issuance of this report 29 May 2006 (29.05.2006)</p> <p>Authorized officer Agnes Wittmann-Regis</p> <p>Telephone No. +41 22 338 89 70</p>
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

9/16

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/013535

International filing date (day/month/year)
29.11.2004

Priority date (day/month/year)
28.11.2003

International Patent Classification (IPC) or both national classification and IPC
A61K38/00, C12N5/10, G01N33/50, A61P3/10

Applicant
DEVELOGEN AKTIENGESELLSCHAFT FÜR...

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/013535

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☒ in written format
☒ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☒ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 1-57

because:

- ☒ the said international application, or the said claims Nos. 53-57 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-57 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☒ the claims, or said claims Nos. 1-57 are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|------------------------------------------------------------|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☒ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/013535

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	-
	No: Claims	-
Inventive step (IS)	Yes: Claims	-
	No: Claims	-
Industrial applicability (IA)	Yes: Claims	-
	No: Claims	-

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1- Claims 53-57 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).
- 2- Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempt/s to define the subject-matter in terms of the result to be achieved ("DG119-1 agonist", "DG119-2 antagonist"), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

The same applies to claims 2-57.

- 3- Furthermore, second medical use claims 1-10, 13-25 are not acceptable under Art. 6 PCT. The therapeutic application is functionally defined by a mechanism of action ("stimulate and / or induce the differentiation or development of insulin producing cells from progenitor cells" or "promote the protection survival and / or regeneration of insulin producing cells") which does not allow any practical application in the form of a defined, real treatment of a pathological condition (disease).
- 4- Furthermore, the term "product" ("a DG119-1" product) is not clear (Art. 6 PCT). The term "variants" is also unclear, so that claims 1-1-57 further lack clarity.
- 5- The present application provides no example of agonists of DG119-1 or of DG119-2. Furthermore, there is no demonstration in the present application that the claimed uses have indeed the alleged effects.

The claims lack therefore clarity, support and disclosure, since the skilled person, after reading the description, would not be able to perform the invention over the whole area claimed without undue burden and without needing inventive skill (Arts. 5 and 6 PCT).

Indeed, the claims encompass a genus of compounds defined only by their function wherein the relationship between the structural features of the members of the genus and said function have not been defined.

In the absence of such a relationship either disclosed in the application as originally filed or which would have been recognised based on information readily available to the skilled man, the skilled person would not know how to make and use compounds that lack any structural definition. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

These claims are so called "reach-through" claims wherein protection is sought for embodiments not yet identified. No examples are provided in the application as originally filed for the claimed "products", agonists, antagonists other than the sequences of DG119-1A1A, DG119-1B1B, DG119-2A2A and DG119-2B2B, hence no claims to such general products nor their possible uses can be allowed.

- 6- The reference to GenBank Accession Number XP_03400 in claim 17 renders said claim unclear (Art. 6 PCT). Furthermore, the term "substantially homologous" is not clear (Art. 6 PCT).
- 7- Although claims 1, 6, 26, 35, 39, 40, 50, 52, 53, 56 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.
- 8- Hence, in view of the above, no opinion is to be formulated for the subject matter of present claims 1-57 which do not meet the requirements of Arts. 5 and 6 PCT. For the sake of completeness, some remarks are made under item V (see below).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability;

citations and explanations supporting such statement

9- Reference is made to the following documents:

- D1: GÜNTHER KARMANN, CEO: "DeveloGen AG European Leader in Metabolic Disorders" 11 November 2004 (2004-11-11), XP002324340 ZÜRICH Retrieved from the Internet: URL:http://www.sbmd.ch/downloads/Presentations/DeveloGen_041111.pdf [retrieved on 2005-04-13]
- D2: DATABASE EPO Proteins [Online] 14 January 2004 (2004-01-14), "Sequence 51 from Patent WO03099318." XP002324341 retrieved from EBI accession no. EPOP:AX959755 Database accession no. AX959755
- D3: DATABASE EPO Proteins [Online] 14 January 2004 (2004-01-14), "Sequence 52 from Patent WO03099318." XP002324366 retrieved from EBI accession no. EPOP:AX959756 Database accession no. AX959756
- D4: DATABASE GENBANK [Online] 17 October 2003 (2003-10-17), "similar to RIKEN cDNA 4832415H08 gene [Homo sapiens]." XP002324343 retrieved from GENBANK accession no. GI:37548656 Database accession no. XP_034000
- D5: DATABASE GENBANK [Online] 5 October 2003 (2003-10-05), "hypothetical protein LOC169611 [Homo sapiens]." XP002324344 retrieved from GENBANK accession no. GI:32698795 Database accession no. NP_872293

- 10- Claims of broad scope are not allowable if the skilled person, after reading the description, is not able to perform the invention over the whole area claimed without undue burden and without needing inventive skill. Furthermore, the subject matter of a particular claim can be regarded as inventive only if all the embodiments covered are shown to provide a solution to the technical problem posed. This is not the case of the present application, which provides no data on the alleged effectiveness of the compounds which use is claimed.
- 11- When / if carrying out amendments, and in order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate precisely

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/013535

the passages of the application as filed on which these amendments are based (also rule 66.8 (a) PCT).

Only amendments with a clearly identified basis on the application as originally filed will be taken into account for the international preliminary examination report.